June 22, 2007
US Serial No. 09/835,537

REMARKS

Claims 19 and 21 - 35 are still pending.

In the Office Action, the rejections of claims 19 and 21 – 35 under 35 USC §112, first paragraph, as well as under §102(e) and §103(a) over Kaddurah-Daouk, were maintained. These rejections are again respectfully traversed, as further explained and argued below.

The Office Action states that the claims recite a 'guanidine salt', which is contended by the Examiner to include 'guanidinoacete'. The Examiner further states that " guanidinoacetate is assumed to be guanidine acetate absent a showing that the structures differ."

This incorrectness of this assumption should be once and for all be put to rest. Applicants state once again, ***there is no such molecular entity possible as 'guanidine acetate'***. Thus, the difference in structures cannot be shown, because ***there is no structure*** of 'guanidine acetate'. As stated in Applicants' remarks in past responses to these rejections, guanidine is a strong base and as such ***cannot form a salt with an acetate moiety***. Therefore, Applicants again urge that the rejections under §112, §102 and §103, must be withdrawn on the basis of the clear facts.

The only remaining rejection is of claims 19, 23-29 and 31 under §102(b) and §103(a) over Azumendi (GB 2315672). In view of the Examiner's arguments on page 3 of the Office Action, Applicants request that this rejection be withdrawn on the basis of the following remarks.

First, the Office Action states under "(c)" on page 3 that both Azumendi and the rejected claims comprise the same active step of administering KI or NaI to mammals, and that therefore both inventions would induce hyperthermia. Applicants reiterate from their response of November 27, 2006, that the aspect of hyperthermia in accordance with the present invention as claimed and disclosed is a separate, optional component of treatment. **The chaotropic agents *do not inherently* induce hyperthermia**. Please refer to the paragraph bridging pages 14 and 15 of the instant specification, where the aspect of hyperthermia treatment is disclosed. The induction of hyperthermia is a way to enhance the treatment with the chaotropic agents; it is a separate, adjuntive part of the treatment. As disclosed, such hyperthermia can be induced by the application of heat to the body from external heat sources. Therefore, this aspect of the Examiner's argument is simply incorrect. Azumendi does not disclose this aspect of the present invention at all.

Second, the Office Action states under "(d)" on page 3 that Azumendi discloses treating prion diseases such as BSE or CJD by administering KI or NaI to the affected mammal. Applicants submit, however, that in actuality Azumendi does not teach the treatment of prion diseases with KI or NaI at all, and that this is a misinterpretation of the reference. Simply stated, the published UK patent *application of Azumendi would not be interpreted by one skilled in the art as teaching a method of treating prion diseases* by administering NaI or KI.

One skilled in the art would clearly recognize that Azumendi's disclosure relates to the *treatment of protozoa cysts*, such as those of Sarcocystis protozoa, which cause the condition "Sarcocystosis" in mammals. According to Azumendi's disclosure at page 4, lines 27 – 29, Sarcocystis infection results in muscle spasms, diarrhea and chronic fatigue; Azumendi *speculates* that, since such symptoms are also present in demylinating diseases such as multiple sclerosis, then such demylinating diseases must also be caused by Sarcocystis infection (page 4, lines 30 – 32), and possibly by an isolated toxin of the Sarcocystis protozoa (page 4, lines 32 – 35). *Azumendi goes on to theorize that such demylinating diseases could also be treated by treating a* ***supposedly underlying*** *protozoal infection.*

At page 5, lines 9 – 20, Azumendi *overreachingly proposes* that, because of a "*close* ***similarity of characteristics*** *between the...prion and the toxin*", the prion entity and the Sarcocystis toxin must be one and the same! On such a theory, Azumendi speculates that the treatment he discloses for treating a ***supposedly underlying protozoal infection*** will also be effective in treating prion diseases such as BSE and CJD.

Such assumptions and theories by Azumendi are clearly flawed, however. For one thing, Azumendi does not even disclose what the "similarity of characterics" between the toxin and prion protein are. For instance, he does not mention anything about similar activities or structural similarities of the two entities.

In other words, Azumendi is ***incorrectly concluding that prion diseases are caused by Sarcocystis infection***. In fact, Azumendi's entire disclosure and claims ***require the presumption that what is being treated is the protozoal infection itself***. The hypothesis that protozoal infection causes diseases such as CJD or BSE ***has never been proven***, and it is not a view held by scientists in the area of prion diseases. At the time of the present invention, it was generally accepted that the ***prion protein is the causative agent of prion diseases*** such as CJD. ***Protozoal infection has never been shown to be the cause of prion diseases.***

Accordingly, it is only proper that the rejection under §102(b) and §103(a) over Azumendi be reconsidered and withdrawn.

Applicants respectfully submit that claims 19 and 21 – 35 are in condition for allowance.

With their reponse filed November 27, 2006, Applicants submitted a Notice of Appeal. Applicants assume, therefore, the the Notice of Appeal was held in abeyance. Since this Office Action was subsequently issued, Applicants request that the previously filed Notice of Appeal (and fee paid) now be re-dated as of the date of submission of this paper (June 22, 2007) and be made of record. Accordingly, Applicants' appeal brief will now be due 2 months from now, or August 22, 2007. with the submission of this paper. In addition, Applicants request an appeal conference with the Examiner in order to expedite the disposition of this application.

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A Petition for two-month extension of time is also submitted with this paper.

Respectfully submitted,

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Enclosures: Petition for Extension of Time